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## **REMARKS**

### **I. Petition for Extension of Time**

Applicants herewith petition the Commissioner for Patents to extend the time for response to the Office Action mailed 15 September 2008 for two (2) months from 15 December 2008 to 15 February 2009. Authorization is given to charge the extension of time fee of \$490.00 (37 C.F.R. §1.136 and §1.17) to Deposit Account No. 23-1703. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

### **II. Amendments**

Claim 1 has been amended to recite that the first solution and aqueous phase are combined under rapid mixing to form a dispersion of amorphous particles. Support is provided by the paragraph bridging pages 9-10 of the specification as filed and by original claim 11 which has been canceled. Claim 1 has also been amended to recite that the nanocrystalline particles prepared by the claimed process have a mean particle size of 10 to 280 nm. Support is provided by the specification at page 4, line 29. The dependency of claim 12 has been amended in view of the cancellation of claim 11. Claim 17 has been amended to clarify that the isolation step of the claimed process occurs after the nanocrystalline particles have been formed or after the nanocrystalline particles have been formed and the water-miscible organic solvent has been removed. Support is provided by the specification at page 17, lines 8-10.

The specification has been amended to provide an abstract of the disclosure as required by 37 C.F.R. §1.72(b). Support is provided by the abstract appearing on the cover page of WO 2004/009057 which is the published PCT application from which the referenced national phase application is derived.

Applicants submit that the claim amendments are fully supported by the specification and do not introduce new matter.

### **III. Information Disclosure Statement**

The Examiner states that the Information Disclosure Statement ("IDS") filed 7 July 2008 fails to comply with 37 C.F.R. §1.98(a)(2) which requires a legible copy of each filed cited foreign patent document, non-patent literature publication or portion thereof, and all other information or portion thereof that caused it to be listed. Other than the U.S. patent documents

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identified in that IDS, the Examiner states that the other information referred to therein was not considered.

Applicant's agent confirms that each of the non-U.S. patent documents cited in the IDS are available on PAIR in the IFW of the subject application. The IFW also contains an EFS Acknowledgement Receipt acknowledging the successful transmission of the non-U.S. patent documents identified in the IDS.

Accordingly, Applicants submit that the IDS filed 7 July 2008 complies with 37 C.F.R. §1.98(2). The Examiner is, therefore, requested to consider all of the information referred to in that IDS and provide Applicants - and the record - with confirmation that the Examiner has considered this information.

#### **IV. Claim rejection – 35 U.S.C. §112**

Claims 4, 5 and 17 are rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. The objected phrase "the combined solution" has been deleted from claim 4 which has been amended to refer to the aqueous medium following step (a) of claim 1. The preamble of claim 1 provides antecedent basis for the expression "the aqueous medium". Support for amended claim 4 is also found at page 17, lines 4-7, of the specification. Claim 17 has been amended to clarify when the isolation step of the claimed process occurs. The expression "aqueous medium" as recited by claim 17 has been deleted from the claim 17 without any loss of clarity.

For all of the foregoing reasons, withdrawal of the §112 rejections is requested.

#### **V. Claim rejections – 35 U.S.C. §102**

##### **a. WO 00/44468**

Claims 1, 3, 6, 12, 14 16 and 17 are rejected under 35 U.S.C. §102(b) as being unpatentable in view of WO 00/44468 to Lindrud et al. ("Lindrud").

The claimed invention is directed to a process for preparing a dispersion of nanocrystalline particles in an aqueous medium comprising combining a first solution comprising a substantially water-insoluble substance in a water-miscible organic solvent with an aqueous phase comprising water and, optionally, a stabilizer. Surprisingly and advantageously,

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the inventors have found that the rapid combination of the first solution and aqueous phase promotes the formation of small amorphous particles (p. 9, lines 29-30). Without wishing to be bound by theory, it is thought that the formation of the initial suspension of amorphous particles following combination of the first solution with the aqueous phase, as claimed, promotes the subsequent formation of a uniform dispersion of nanocrystalline particles during the subsequent sonication. As demonstrated by the Examples, nanocrystalline particles having a mean particle size of 10 to 280 nm are obtained with the claimed process.

In contrast to the claimed invention, Lindrud does not disclose a step for forming a dispersion of amorphous particles. Rather, Lindrud is directed to a continuous crystallization process (p. 2, lines 24-28) which involves the formation of a crystallization slurry (p. 5, lines 9-11). Lindrud applies ultrasound energy to the continuous crystallization process to form crystals having a diameter of less than one micron (Abstract; Examples 1 and 2).

Anticipation requires that the cited prior art describe each and every feature of the claimed invention. Lindrud does not disclose the claimed process step of forming a dispersion of amorphous particles. Nor does Lindrud disclose a process for obtaining nanocrystalline particles having a mean particle size of from 10 to 280nm. For all of the foregoing reasons, Lindrud fails to anticipate the claimed invention. Withdrawal of the §102 rejection in view of Lindrud is requested.

b. US 6,607,784

Claims 1, 3-9, 12, 14-16, 18 and 19 are rejected under 35 U.S.C. §102(e) as being unpatentable in view of US 6,607,784 to Kipp et al. ("Kipp").

Kipp is directed to a method for preparing submicron sized particle of an organic compound having an average effective particle size of 400 nm to 2 microns (Abstract).

As amended, claim 1 is directed to a process comprising rapid mixing to obtain a particle size of from 30-280 nm as claimed. Although Kipp states at column 4, line 55, that a particle size of less than 400 nm is preferable, Kipp does not provide an enabling disclosure for obtaining a particle size less than 400 nm. Accordingly, Kipp fails to anticipate the claimed invention. Withdrawal of the §102 rejection in view of Kipp is requested.

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**VI. Claim rejections – 35 U.S.C. §103**

**a. WO 00/44468**

Claims 11-13, 15 and 18 are rejected under 35 U.S.C. §103(a) as being unpatentable in view of WO 00/44468 to Lindrud et al. ("Lindrud").

Applicants rely on the arguments set forth in the preceding Section V(a) with regard to the §102 rejection in view of Lindrud.

Lindrud does not suggest the claimed process step of forming a dispersion of amorphous particles. Nor does Lindrud suggest the advantageous effect on reducing mean particle size by forming an initial suspension of amorphous prior to sonication. For all of the foregoing reasons, a *prima facie* case of obviousness has not been established. Withdrawal of the §103 rejection in view of Lindrud is requested.

**b. US 6,607,784**

Claims 1-16 and 18-20 are rejected under 35 U.S.C. §103(a) as being unpatentable in view of US 6,607,784 to Kipp et al. ("Kipp").

Applicants rely on the arguments set forth in the preceding Section V(b) with regard to the §102 rejection in view of Kipp.

Kipp states at column 4, line 55, that a particle size of less than 400 nm is preferable. However, as acknowledged by the Examiner, Kipp does not show how to obtain a particle size less than 400 nm. Furthermore, none of Examples 1-4 of Kipp shows rapid mixing. Although Kipp states at column 7, lines 30-31 that the addition rate is dependent on the batch size and precipitation kinetics for the organic compound, Kipp does not suggest that rapid mixing provides a particle size of from 30-280nm as claimed.

Therefore, even if it were possible to modify the process of Kipp as alleged by the Examiner, it cannot be said in the absence of hindsight that Kipp, at the time the claimed invention was made, suggested rapid mixing to form an initial dispersion of amorphous particles to obtain nanocrystalline particles having a mean particle size of from 10 to 280nm. Is the Examiner saying that routine experimentation is sufficient to establish nonobviousness? Kipp is silent that rapid mixing is an essential process step to the unexpected and advantageous formation of nanocrystalline particles having a mean particle size of from 30-280 nm as claimed.

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The obtainment of an unexpected and advantageous result, as with the claimed invention, is the correct standard of obviousness.

For all of the foregoing reasons, therefore, a *prima facie* case of obviousness has not been established. Withdrawal of the §103 rejection in view of Kipp is requested.

**CONCLUSION**

For all of the foregoing reasons, Applicants submit that claims 1-10 and 12-20 are in condition for allowance which action is earnestly solicited.

Any fee due in connection with this response should be charged to Deposit Account No. 23-1703.

Dated: 10 February 2009

Respectfully submitted,

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